STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
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May 11, 2005

TO: Washington State Board of Health Members

FROM: Dr. Tom Locke, Board Chair

SUBJECT: **UPDATE ON NEWBORN CYSTIC FIBROSIS SCREENING AND THE ACMG REPORT**

Summary

A technical review committee of seven experts in public health and cystic fibrosis met on April 9, 2005. The committee's charge was to review current scientific and medical evidence regarding newborn screening for cystic fibrosis against the State Board of Health's five criteria for adding disorders to the state's mandatory screening program. The committee was asked if the evidence was sufficiently compelling to justify convening a broadly representative Newborn Screening Advisory Committee to review all of the issues and make a formal recommendation to the Board as to whether cystic fibrosis should be added to the state's mandatory requirements. The technical review committee unanimously concluded that the research evidence is in sync with the criteria and that a full advisory committee should be convened by July 2005 to further review the issues and make recommendations to the Board. (See Finding from the Technical Review Committee behind Tab 13 for more details.)

Today, I have invited Dr. Maxine Hayes, State Health Officer, and Mike Glass, Director of the Washington State Newborn Screening Program, to talk about the recommendations from the cystic fibrosis technical review committee. On April 27, 2005 Dr. Hayes and I met with staff to begin to plan our review of the American College of Medical Genetics (ACMG) report. Dr. Hayes and Mr. Glass will also introduce us to the ACMG report and some of its key findings. (See the ACMG recommendations and the summary report behind Tab 13 for more details).

Recommended Board Action

None at this time.

Cystic Fibrosis Background

Dr. Hayes and I co-chaired the Newborn Screening Advisory Committee, which concluded its work in 2002. This committee of experts was given a two-fold charge: (1) develop criteria to apply to any new additional screenings added to the required list and (2) engage in a deliberative process to consider

amending the newborn screening rule to determine which, if any, additional disorders should be included in mandatory screening and to examine the adequacy of existing privacy protections.
In 2003 the Newborn Screening Advisory Committee made a number of recommendations to the Board. As a result, the Board adopted five criteria for evaluating any additional mandated newborn screenings and accepted a recommendation to begin screening for five new disorders. Although the committee did not recommend adding cystic fibrosis to the list at that time, it strongly encouraged the Board to re-evaluate this decision in 2 years when the results of several additional studies on early cystic fibrosis treatment would be available. Since 2002, several studies have shed new light on therapeutic interventions and cost benefit/cost effectiveness of cystic fibrosis treatment.

At our Board meeting in December 2004, a motion was passed to work with the Department of Health to convene a panel of technical experts to review new information available on the benefits of newborn screening for cystic fibrosis and make a preliminary determination whether this condition meets criteria established for newborn screening tests in Washington. If it meets the criteria, a Newborn Screening Advisory Committee should be convened to make recommendations to the Board regarding inclusion of cystic fibrosis on the list of mandated newborn screening tests.

American College of Medical Genetics Background

Medical and technological advances in recent years have made it feasible to screen newborns for an increasing number of disorders. More disorders can be detected using the same dried blood specimen that is routinely collected to test infants in Washington State. In 2004, the United States Department of Health and Human Services' Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children accepted a report that had been commissioned by the ACMG. This report recommends 29 disorders for newborn screening. Eighteen of these twenty-nine disorders (including hearing loss and cystic fibrosis) are currently not screened for in Washington State.

At our Board meeting in December 2004, a motion was passed to request that the Department of Health review the ACMG report when it is released to determine if there are effective interventions available for the 16 new conditions and to give the Board a preliminary assessment of associated costs, Washington State's tandem mass spectrometry capacity, and the number of newborns in Washington State who could be potentially identified with these conditions.